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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,102	12/27/2004	Imao Mikoshiba	Q85257	9490

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
12/22/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/519,102	MIKOSHIBA ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,14,24 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 14, 24, 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed August 31, 2009 has been received and entered into present application. No claims were canceled or added by applicant. Thus claims 12, 14, 24, and 34-36 are pending.

Applicants' arguments, filed August 31, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Declaration

Applicant submitted arguments in defense of the declaration by Yuji Kiyono filed December 08, 2008 and cites Ojima et al. (Folio Pharmacol. Jpn.) as evidence that insulin secretion by administration of a drug occurs in a similar fashion to diabetic rats and normal animals. It is firstly noted that only the abstract and the figure captions are in English and only the English portions of the references could be considered by the examiner. Contrary to applicant's assertions Ojima et al. does not state or show that insulin secretion is the same in diabetic and normal animals. In fact they show that they react differently. In figure 6A (normal rats) they show that insulin secretion by mitiglinide rats is higher than that of the control and that the peak is at 15 minutes after mitiglinide administration. In figure 9B (diabetic rats) the level of insulin secretion in the control is

actually higher than the mitiglinide treated diabetic rats and the peak level does not occur until 1 hr. This indicates not only do diabetic rats respond differently to the mitiglinide their response is delayed compared to normal rats. That data of figures 6A and 9B supports the examiner's argument that there is a significant difference between the response of a diabetic versus normal rat or human.

Confusingly applicant has also provided figures A and B (discussed on page 7 of remarks) that it appears applicant has created based on figures 6(A) and 9 (B) of Ojima et al. It is not clear how applicant generated such figures as there was not raw data available. However, even if the graphs of figures A and B were to be accurate comparing the normal rats to diabetic rats under control demonstrates that not only do the diabetic rats have less of a response (insulin secretion) their response is delayed which further supports the examiner's position. In the mitiglinide treated rats the diabetic rats have a delayed and less strong insulin secretion response which further demonstrates that testing done on normal rats would not give accurate description of the effect on a diabetic rat (or human). Thus the examiner maintains her position that the Declaration by Yuji Kiyono filed December 08, 2008 is not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 14, 24, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ichikawa et al. (Clinical and Experimental Pharmacology and Physiology, already of record on pages 4-6 of the previous office action dated March 04, 2009 the reasons of which are herein incorporated by reference) in view of Sugiyama et al. (US 2003/0040490 A1, cited on applicant's IDS).

Claims 12, 14, 24, and 34-36 were previously rejected over Ichikawa et al. on pages 4-6 of the office action dated March 04, 2009, the reasons of which are incorporated by reference. Applicant has argued that the 0.3-3 mg/kg range does not render their claimed 10 or 11 mg range obvious. They argue that 0.3 mg/kg dosage is not effective and that the lowest dosage one would use from Ichikawa et al. is 1 mg/kg which for a 55 kg patient would be 55 mg. Firstly, Ichikawa et al. never says that the 0.3 mg/kg was ineffective. However, they do focus on the 1 mg/kg and 3 mg/kg dosages and disclose a dose dependent reduction on blood sugar (page 425, first column). In

figure 1A, the 0.3 mg/kg is reduced over the control, and statistically significant reduction at 30 minutes although the reduction at 1 hr might not be statistically significant. The examiner does not agree that one of ordinary skill in the art would read Ichikawa and assume that 0.3 mg/kg cannot be used, however it is acknowledge that they might assume a higher dosage would be more effective. It is important to remember that the data and testing in Ichikawa et al. is done on rats and not on humans so any dosages taught by Ichikawa et al. would need to be optimized for human treatment. It is reasonable that higher dosages are given to rats per kg body weight because they do not have the issues of adverse events and patient compliance. Safety is not as much of an issue with rats, while with humans there is a strong desire to use the smallest amount of an active agent necessary to achieve the desired result. In looking to optimize this treatment suggested by Ichikawa et al. for humans one of ordinary skill in the art would look to dosages of mitiglinide given to humans. Sugiyama et al. teaches 10 mg of mitiglinide 3 times daily before meals (page 3, [0065]). They even disclose treatment of both type 1 and 2 diabetes with their composition (page 4, [0075]). It would have been obvious to one of ordinary skill in the art at the time of the invention that in optimizing treatment for humans that 10 mg three times per day with meals as suggested by Sugiyama et al. would be an excellent starting point for treatment with humans as it is being used to treat diabetes as well. Additionally, Sugiyama et al. teaches 1-10 mg as their preferred range (page 3, [0065]) and thus dosages even lower than 10 mg can be effectively used so one of ordinary skill in the art would not believe that higher dosages were required to have an effect in humans.

Thus claims 12, 14, 24, and 34-36 are unpatentable over Ichikawa et al. in view of Sugiyama et al.

Applicant has not perfected priority to their Japanese priority document which is only provided in Japanese thus the current effective filing date is June 26, 2003 and Sugiyama et al. applies as prior art.

Conclusion

No claims are allowed.

Sugiyama et al. was added to the previous 35 USC 103 rejection to strengthen the rejection, because this change was not necessitated by amendment to the claims this action is non-final.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Examiner, Art Unit 1614